

CENTRAL MARKS DEPARTMENT-2

Ref: CMD-II/16:14625

27 11 2015

Subject: Switchover guidelines for revised Indian Standard Specification IS 14625:2015 for Plastic Feeding Bottles.

1. Indian Standard Specification for **Plastic Feeding Bottles** as per **IS 14625:1999** has been revised as **IS 14625:2015 for Plastic Feeding Bottles**. The concurrent running of the previous version of the standards is permitted upto 19 February 2016 as per the gazette notification dated 19.08.2015 . All ROs /BOs have also been informed vide our mail dated 04.09.2015 to bring the revised standard and the date of cancellation of the earlier version of the standard i.e. on 19 02 2016 to the notice of the concerned licensees/applicants.
2. The main changes effected in revised **IS 14625:2015** are as follows :

(i) All modifications carried through 5 amendments issued on existing version have been incorporated.

(ii) Use of polycarbonate as a material for manufacturing infant feeding bottles have been deleted.

(Please refer Foreward of IS 14625:2015)

(iii) The requirement of migration of certain elements mentioned at Table-1 of ISS for heavy metals, antimony, arsenic, chromium, mercury, cadmium, lead, barium & selenium has been incorporated.

3. Revised STI, Doc:STI/14625/5, November 2015 taking into consideration all the changes introduced in the revised standard IS 14625:2015 is enclosed.

4. In order to implement the revised Standard vis-a-vis Scheme of Testing and Inspection, following procedure shall be adopted:

For existing licensee:

- (i) Endorsement in the licence as per revised standard shall be made after obtaining the following documents from the licensees:
 - (a) Declaration regarding availability of testing equipment as per revised specification on CMD/PF 306.
 - (b) Acceptance of revised STI.
 - (c) Test report indicating conformity of the product to the revised specification (In-house factory test report/independent test report)
- (ii) An early inspection shall be planned to verify the availability of testing equipment as per revised standard with the licensees after obtaining declaration on CMD/PF 306. During the inspection sample shall be drawn for independent testing to ensure conformity of the product to the revised standard.

- (iii) Action shall be taken as per OMPC 2004, if the licensee fails to submit the acceptance of STI in stipulated time. Likewise, in case sample drawn during inspection fails in factory/independent testing as per the revised version, further actions are to be taken as per OMPC 2004.

For Applicants:

- (i) All new applications may be recorded and processed as per revised **IS 14625:2015**.
 - (ii) In case applicant sample is already tested, the GOL shall be processed as per as per the old/revised version of the Specification as requested by the firm. However, in case the GOL has been processed as per the old version of the Specification, an undertaking shall be obtained from the firm that the actions required as per revised **IS 14625:2015** shall be completed before 19 February 2016.
 - (iii) In case applicant sample is yet to be tested by Lab, necessary action may be taken immediately by BO for considering the case as per **IS 14625:2015** after consulting the applicant.
7. Revised STI Doc: **STI/14625/5, October 2015** will be implemented and will run concurrently with the earlier version of the STI till 19 February 2016 after which the earlier version of the STI will cease to exist.

Submitted for approval please

(V K Diundi)
Sc.F(CMD-II)

Head CMD-II

All ROs/BOS

केन्द्रीय मुहर विभाग-2

संदर्भ : सीएमडी-2/16:14625

30 11 2015

विषय : संशोधित भारतीय मानक आइ एस : 14625 :2015 “प्लास्टिक की दूध पिलाने की बोतलों” के लिए ड्राफ्ट अंतरण दिशानिर्देश

1. आइ एस 14625 :1999 प्लास्टिक की दूध पिलाने की बोतलों के लिए भारतीय मानक आइ एस : 14625 :2015 के रूप में संशोधित किया गया है । राजपत्र अधिसूचना दिनांक 19 08 2015 के अनुसार पिछले संस्करण के साथ समवर्ती संचालन की अनुमति 19 फरवरी 2016 तक दी गयी है । हमारी ईमेल दिनांक 04-09-2015 के द्वारा सभी क्षेत्रिय/शाखा कार्यालयों को सूचित किया गया है कि संशोधित मानक तथा पिछले संस्करण के रद्द होने की तिथि जो कि 19 02 2016 है, को सभी संबंधित लाइसेंसधारकों/आवेदकों के ध्यान में लाया जाए ।
2. **संशोधित मानक आइ एस : 14625 :2015 में प्रभावित मुख्य परिवर्तन इस प्रकार है :**
 - 1) मौजूदा संस्करण में पिछले संस्करण में जारी 5 संशोधनों के माध्यम से किए गए सभी संशोधनों को शामिल किया गया है ।
 - 2) शिशु को दूध पिलाने की बोतलों के विनिर्माण के लिए एक सामग्री के रूप में पॉलीकार्बोनेट का उपयोग हटा दिया गया है. (कृपया आइ एस : 14625 :2015 का फोर्वरड देखें) ।
 - 3) भारी धातुओं, Antromony, आर्सेनिक, क्रोमियम, पारा, कैडमियम, सीसा, बेरियम और सेलेनियम के लिए आइ एस एस कि तालिका-1 में उल्लिखित कुछ तत्वों के प्रवास की आवश्यकता को शामिल किया गया है ।
3. संशोधित मानक आइ एस : 14625 :2015 में प्रस्तावित सभी परिवर्तनों को ध्यान में रखते हुए मसौदा एस टी आइ DOC:STI/14625/5, अक्टूबर 2015 को पहले से ही 05 11 2015 को परिचालित किया गया है ।
4. संशोधित मानक की तुलना में परीक्षण और निरीक्षण की योजना को लागू करने के लिए निम्न प्रक्रिया अपनाई जाएगी :
मौजूदा लाइसेंसधारकों के लिए :
 - i) संशोधित मानक के अनुसार लाइसेंस में पृष्ठांकन निम्नलिखित दस्तावेज प्राप्त करने के बाद ही किया जायेगा :
 - a) संशोधित मानक के अनुसार सीएमडी/पीएफ 306 पर परीक्षण उपकरणों की उपलब्धता के बारे में घोषणा

- b) संशोधित एस टी आइ की स्वीकृति
- c) संशोधित मानक के अनुसार उत्पाद की अनुरूपता को दर्शाती टैस्ट रिपोर्ट (इन हाउस टैस्ट रिपोर्ट/स्वतंत्र जांच रिपोर्ट)
- ii) सीएमडी/पीएफ 306 पर घोषणा प्राप्त करने के बाद लाइसेंसधारकों के पास संशोधित मानक के अनुसार परीक्षण उपकरणों की उपलब्धता को सत्यापित करने के लिए एक निरीक्षण की योजना बनाई जायेगी। निरीक्षण के दौरान, संशोधित मानक के अनुसार उत्पाद की अनुरूपता सुनिश्चित करने के लिए, स्वतंत्र जांच के लिए नमूना लिया जायेगा।
- iii) अगर लाइसेंसधारी निर्धारित समय में एस टी आइ की स्वीकृति प्रस्तुत करने में असमर्थ रहता है तो OMPC 2004 के अनुसार कार्यवाई की जाएगी। इसी तरह अगर संशोधित मानक के अनुसार निरीक्षण के दौरान लिया गया नमूना फैक्टरी/स्वतंत्र जांच में फेल हो जाता है तो आगे की कार्यवाई OMPC 2004 के अनुसार की जाएगी।

आवेदको के लिए :

- i. सभी नए आवेदन संशोधित आई एस 14625:2015 के अनुसार रिकॉर्ड और प्रोसेस किए जाए।
 - ii. अगर आवेदक के नमूने का पहले ही परीक्षण किया जा चुका है और उस मामले में आवेदक के अनुरोध पर लाइसेंस के अनुदान पर कार्यवाई पुराने संस्करण के अनुसार कर ली गई है तो उस मामले में फर्म से एक अंडरटेकिंग ली जायेगी कि वह संशोधित संस्करण आई एस 14625:2015 के अनुसार जो भी कार्य आवश्यक हैं उन्हें 19 फरवरी 2016 से पहले पूरा कर लेगा।
 - iii. अगर आवेदक का नमूना लैब द्वारा परीक्षण किया जाना अभी बाकी है उस मामले में आवेदक से परामर्श के बाद मामले पर तुरंत आई एस 14625:2015 के अनुसार विचार किया जा सकता है।
5. संशोधित एस टी आई DOC:STI/14625/5 , अक्टूबर 2015 लागू की जाएगी और पिछले संस्करण की एस टी आई के साथ 19 फरवरी 2016 तक चलेगी जिसके बाद पिछले संस्करण की एस टी आई का असितत्व समाप्त हो जायेगा।

अनुमोदन के लिए प्रस्तुत है।

(वी के डियुंडी)
वैज्ञानिक एफ

डी डी जी (प्रमाणन)

**SCHEME OF TESTING AND INSPECTION
FOR CERTIFICATION OF
PLASTIC FEEDING BOTTLES
ACCORDING TO IS 14625:2015
(First Revision)**

- 1.0 Laboratory** - A laboratory shall be maintained which shall be suitably equipped and staffed to carry out the different tests in accordance with the methods given in the Indian Standards.
- 2.0 Test Records** - All records of analysis and tests shall be kept in suitable forms approved by the Bureau of Indian Standards.
- 2.1** Copies of any records or charts that may be required by the Bureau shall be made available at any time on request.
- 3.0 Quality Control** - It is recommended that, as far as possible, Statistical Quality Control (SQC) methods may be used for controlling the quality of the product as envisaged in this scheme [See IS 397 (Part 1), IS 397 (Part 2) and IS 397 (Part 3)].
- 3.1** All the testing instruments/equipment are required to be brought under calibration control, as per frequency to be decided depending upon the usage.
- 3.2** In addition, effort should be made to gradually introduce a Quality Management System in accordance with IS/ISO 9001.
- 4.0 Standard Mark** -The Standard Marks(s) as given in Column (1) of the First Schedule of the licence shall be permanently printed on each bottle packed in the carton to which this mark thus applied conforms to every requirement of the specification.
- 5.0 Marking** – In addition, the following markings shall be given as per clause 7.2 of IS 14625:2015.
- 5.1** Each bottle shall be permanently marked with scale mark.
- 5.2** Each carton containing the bottle shall be permanently marked with the following
- a) Name of the product; Plastic feeding Bottles (excluding teats);
 - b) Material – Polypropylene (PP) /Polyethersulfone (PES), olefin based polymer, Co-polyester material or other raw material given in Annex A of standard.
 - c) Indication of the source of manufacture and trade-mark, or the company responsible for placing the product in the market, if any;
 - d) Nominal capacity;
 - e) Batch No. and Code No;
 - f) Month and year of manufacture;
 - g) Name and address of manufacturer;
 - h) Any other information required by the purchaser;
 - i) The bottle shall be cleaned and sterilized before each use as per manufacturer's instructions and ;
 - j) Made from plastics materials meant for food contact applications indicating material used;

- k) Product symbol in line with IS 14534; and
- l) Instructions for use and hygienic care of the product shall be printed in English/Hindi/regional language and may be included in a separate Leaflet placed in or/on the product as given in 7.2.2.

5.3 Instructions for Use

5.3.1 The following information shall be provided:

- a) Information for the safe use of the product; and
- b) Information on unsuitable common methods of heating which might damage the product.

5.3.2 For re-usable products, the following additional instructions shall be provided:

- a) At least one method of cleaning;
- b) Before first use, clean the product; and

5.3.3 For products with feeding accessories, the following 'WARNINGS' shall be provided in the form given:

For your child's safety and health

WARNING -

- a) Always use this product with adult supervision.
- b) Always check food temperature before feeding.
- c) Keep all components not in use out of the reach of children.

*Note: It is recommended that the supplier of feeding bottles include informative literature to explain the reasons and back ground for these warnings.

5.3.4 Heating in a microwave oven may produce localized high temperatures.

For product where microwave heating is recommended as a suitable method of food preparation the following instruction shall be provided although alternative wording is permitted:

Take extra care when microwave heating. Always stir heated food to ensure even heat distribution and test the temperature before serving.

6.0 PACKING :

The bottles shall be packed as per clause 7.1 of IS 14625:2015.

7.0 Levels of Control – The tests , as indicated in Table 1 and at the levels of control specified therein, shall be carried out on the entire production of the factory covered by this Scheme and appropriate records and charts maintained in accordance with Paragraph 2.0 above. All the production which conform to the Indian Standard and covered by this licence shall be marked with the Standard Mark.

8.0 Control Unit – For the purpose of this scheme, plastic feeding bottles of same nominal capacity and of same material polypropylene (PP) / Polyethersulfone (PES) and or other material as specified in the standard manufactured from the same consignment of raw material in a day/shift (if production is in more than one shift in a day) shall constitute one control unit.

8.1 The number of bare naked plastic feeding bottles in a consignment got manufactured and received from BIS licensee of same nominal capacity and same material manufactured in a day shall constitute one control unit. The moulder shall also provide a test certificate for tests carried out by them in process Quality Control mainly for Design, Shape and Size manufacture, Workmanship, Finish and Appearance, Capacity, Capacity scale (for engraved Bottle only), Neck dimension and Wall thickness. (*see Tables).

8.2 On the basis of test results, decisions regarding conformity or otherwise of a control unit to the given requirement of the specification shall be made.

8.3 In respect of all the clauses of the specification the factory shall maintain appropriate controls and checks to ensure that their product conforms to the various requirements of the specification.

8.4 Only those finished products which meet all the requirements of the specification shall be considered fit for marking with Standard Mark.

9. RAW MATERIAL: The raw material used for manufacturing the Plastic Feeding Bottles and accessories excluding teats shall be in accordance with clause 4.1 of IS 14625:2015. Each consignment of the raw material shall be tested for all requirements and records shall be maintained. No testing is required in case the raw material is supplied with supplier's test certificate.

10.0 ADDITIONAL REQUIRMENTS FOR ECO-MARK (OPTIONAL)

10.1 The product shall conform to the requirements for quality, safety and performance prescribed in the standard.

10.1.1 Environmental Consent clearance as per the provisions of The water (Prevention and Control of Pollution) Act, 1974 and The Air (Prevention and control of pollution) Act, 1981 along with the authorization, if required under The Environment (Protection) Act, 1986 shall be up to date and shall be produced to BIS. Additionally, provisions of Prevention of Food Adulteration Act, 1954 and Drugs and Cosmetic Act, 1940 and Rules thereunder shall also be complied, wherever necessary.

- 10.1.2** The product must display a list of critical ingredients in descending order of quantity present expressed as percent of the total. The list of such ingredients shall be identified by Bureau of Indian Standards.
- 10.1.3** The product packaging shall display in brief the criteria based on which the product has been labeled as Environment friendly.
- 10.1.4** The product used for product packaging shall be recyclable or biodegradable.
- 10.1.5** It shall also suitably mention that ECO-Mark label is applicable only to the packaging material/package, if content is not separately covered under ECO-Mark. It may be stated that ECO-Mark is applicable to the product or packaging material or both.
- 11.0** **Rejection** – A separate record shall be maintained giving information relating to the rejection of unit of plastic feeding bottles which do not conform to the specification and the method of their disposal. Such material, if packed in containers, shall in no case be stored together with that conforming to the specification.
- 12.0** **Samples** – The licensee shall supply, free of charge, the sample or samples required in accordance with the Bureau of Indian Standards (Certification) Regulations from his factory or godown. BIS shall pay for the samples taken by it from the open market.
- 13.0** **Replacement** – Whenever a complaint is received soon after the goods with the Standards Mark have been purchased and used, and if there is evidence the goods have not been misused, defective goods or their components shall be replaced or repaired free of cost by the licensee in case the complaint is proved to be genuine and the warranty period (where applicable) has not expired. The final authority to judge conformity of the product to the Indian standard shall be with BIS. The firm should have its own complaint investigation systems as per IS/ISO 10002.

In the event of any damages caused by the goods bearing the Standard Mark, or claim being filed by the consumer against BIS Standard Mark and not “conforming to” the relevant Indian Standards, entire liability arising out of such non conforming product shall be of licensee and BIS shall not in any way be responsible in such cases.

- 14.0** **Stop Marking-** The marking of the product shall be stopped under intimation to BIS, if at any time, there is some difficulty in maintaining the conformity of the product to the specification or the testing equipment goes out of order. The marking may be resumed as soon as the defects are removed under intimation to BIS.

The marking of the product shall be stopped immediately if directed to do so by BIS for any reason. The marking may then be resumed only after permission by BIS. The information regarding resumption of marking shall also be sent to BIS.

- 15.0** **Production Data** – The licensee shall send to BIS as per the enclosed proforma to be authenticated by a Chartered Accountant and by the manufacturer by giving an undertaking, a statement of quantity produced, marked and exported by him and the trade value thereof at the end of each operative year of the licence.

IS 14625:2015
PLASTIC FEEDING BOTTLES
TABLE 1 LEVELS OF CONTROL
(Para 6.0 of Scheme of Testing and Inspection)

Test Details				Level of Control		Remarks
Cl.	Requirement	Clause	Test Method Reference	No. of Samples	Frequency	
4.1	Materials	4.1	IS 14625:2015	One	Each Consignment	Each consignment to be accompanied with supplier's test certificate. Otherwise the material shall be got tested from outside lab for conformity to respective IS before use.
4.2	Teats	4.2	IS 3565	One	i) Each consignment ii) Each mix of vulcanize at a time	i) If purchased, each consignment to be accompanied with supplier's test certificate. Otherwise the material shall be got tested from outside lab for conformity to respective IS before use. ii) If produced in house, a) ISI Mark b) In-house testing c) Outside lab d) Supplier's certificate of the material e) Combination of any b to d.
5.1	Physical Requirements					
5.1.1	Description	5.1.1	IS 14625:2015	One/one % of the consignment*	Every hour/every consignment	A drawing incorporating suitable design, shape and size for each capacity shall be prepared & endorsed by both purchaser and manufacturer.
5.1.2	Manufacture, Workmanship, Finish and Appearance	5.1.2.1 5.1.2.2	IS 14625:2015	-do-	-do-	
5.1.3	Wall Thickness	5.1.3	IS 2798	Two/One % of the consignment*	Every hour/every consignment	
5.1.4	Capacity	5.1.4.1	IS 14625:2015	One/one % of the consignment*	Every hour/every consignment	
5.1.4.2	Capacity Scale	5.1.4.2	IS 14625:2015	-do-	-do-	
	Permanency of pigment	5.1.4.2	Annex B of IS 14625:2015	Three	Every seventh control unit	Only for those bottles which have printed scale & graduation

5.2	Chemical Requirements					
5.2.1	Migration of Certain Elements		IS 14625:2015			
	i) Antimony		IS 15303	One	Once in every three months	
	ii) Arsenic		IS 3025 (Part 37)	-do-	-do-	
	iii) Chromium		IS 3025 (Part 52)	-do-	-do-	
	iv) Mercury		IS 3025 (Part 48)	-do-	-do-	
	v) Cadmium		IS 3025 (Part 41)	-do-	-do-	
	vi) Lead		IS 3025 (Part 47)	-do-	-do-	
	vii) Barium		IS 1699	-do-	-do-	
	viii) Selenium		IS15303/IS3025 (Part 56)	-do-	-do-	

Remarks : Wherever sample size is more than one, all the samples shall pass the test.

IS 14625:2015

PLASTIC FEEDING BOTTLES TABLE 1 LEVELS OF CONTROL (Para 6.0 of Scheme of Testing and Inspection)

Test Details				Level of Control		Remarks
Clause	Requirement	Clause	Test Method Reference	No. of Samples	Frequency	
5.3	Performance Requirements					
5.3.1	Environmental Stress - Crack Resistance	Method 1	IS 8747	Five	Every Seventh control unit	One bottle shall be collected every hour subject to minimum five bottles are to be tested from each control unit whichever is higher.
5.3.2	Transparency	Annex C	IS 14625:2015	Three	Once in two month for each material (Polypropylene/ Polyethersulfone / olefin based polymer/co-polyster material or other	

					material as given in Annex A of IS 14625:2015) or change of consignment of material whichever is earlier.	
5.3.3	Leakage Test	5.3.3	IS 14625:2015	Ten	Each control unit	
5.3.4	Drop Test	Annex D	IS 14625:2015	Three	-do-	
5.3.5	Ageing Resistance	5.3.5	IS 14625:2015	Three	Every third control unit	
5.3.6	Compressive Deformation Resistance	Annex E	IS 14625:2015	Three	-do-	
5.3.7	Product Resistance of Printed Containers	14	IS 2798	Three	-do-	
5.3.8	Migration Test		IS 9845	One One	a) Every third control unit with n-heptane as stimulants. b) Once in a fortnight with distilled water as stimulant.	Test to be carried out with both the stimulants.

APPENDIX I
PROFORMA FOR OBTAINING PRODUCTION DETAILS
(Period to be covered by the Report being _____ to _____)*

Name and address of Licensee & CM/L No.

Name of Articles(s) & IS No.

Grade/type/Size/Variety/Class/ Rating

1. Brand/Trade Name(s) of BIS Certification Marked Products
2. Total production of the article(s) licensed for certification marking
 - 2.1 Total production of the article(s) conforming to Indian Standard
3. Production covered with BIS Certification Mark and its approx value
 - a) Quantity
 - b) Value Rs.
 - 3.1 Brand Name used on production covered under BIS Certification Mark
 - 3.2 Calculation of marking fee on Unit-rate basis: Marking Fee per unit
 - a) Unit
 - b) Quantity covered with BIS Certification Mark

*Information to be filled up by BO before forwarding to the licensee.

Note: In case a clause is not applicable, suitable remarks may be given against it.

- c) Marking fee rounded off in whole rupees as obtained by applying unit rates given in (a) on quantity given in (b)

4. Quantity not covered with BIS Certification Mark. If any, and the reasons for such non-coverage

- 4.1 Brand Name under which non certified goods were sold

5. Quantity Exported with BIS Standard Mark and its value
 - 5.1 Brand Name under which BIS Certified goods are exported

6. Authentication by Chartered Accountant

7. Authentication by Manufacturer

(*Information to be filled up by BIS before forwarding to the licensee.)

Note: In case a clause is not applicable, suitable remarks may be given

